

### **Remarks/Arguments**

Favourable reconsideration of this application as now amended is respectfully solicited. Claims 13, 15-20, 31-36, 39, 47 49 and 52-67 are in the case.

In response to the Office Action dated October 19, 2004, Claims 13, 36, and 49 have been amended as set out in the Listing of Claims enclosed herewith. Claims 14, 46, 48, 50 and 51 have been cancelled from the application, and new Claims 62 to 67 have been added to the application. Care has been taken to avoid the introduction of new matter and basis for the amendments made is set out below.

The language of "a holding element" has been deleted from Claims 13, 36, 46, 48, 49 and 50. The amendment of the claims is believed to overcome the Examiner's objection that the amendment filed on June 14, 2004 is not fully responsive.

Claims 13, 36 and 49 have been amended to incorporate the feature that the tubular sleeve, when shortened, can slide along the tube. This feature is described, for example, with reference to Fig. 5b on Page 12 Lines 24 to 28, with reference to Fig. 5g on Page 13 Lines 6-8 and on Page 14 Lines 1-3. Hence the amended claims read on the species of the invention elected in the response to the requirement for the election of species dated May 22, 2002.

Claim 36 has been further amended based on Claim 15 to specify that the tubular sleeve comprises attachment means for attaching the sleeve to a patient, wherein the tubular means is arranged to lengthen and grip the tube when the tube is pulled away from the attachment means.

Claim 49 has also been amended, based on Claim 15 to specify that the tubular sleeve further comprises attachment means for attaching the sleeve to a patient. New Claims 62 to 69 have been added, and bases for these claims can be found in, for example, Figs. 5d to 5l, on Page 12 Line 30 to Page 13 Line 4 and on Page 13 Lines 20-24 of the application.

**Comments relating to the novelty and inventiveness of the amended claims**

Although the Examiner has not raised any anticipation or obviousness objections to the claims in the present Office Action, to assist the Examiner, arguments relating to the novelty and inventiveness of the claims over US 4,867,154 (Potter et al.) and US 4,754,685 (Kite et al.), based on the Examiner's comments in the Office Action of March 12, 2004 are set out below.

**Rejection of the claims under 35 U.S.C 102(b) as being anticipated by Potter et al (US Pat # 4,867,154)**

The claims submitted in the attached Listing of Claims are both novel and non-obvious over Potter et al as set out below.

The Examiner asserts that "Potter discloses an endotracheal tube stabilising device that includes a tubular sleeve fastener." With respect, however, it is not conceded that the support disclosed in Potter comprises a tubular sleeve. The support (element 12 of Fig. 1 and element 68 of Fig. 14) comprises a coiled wire (Column 7 Line 14) having a very open coil with large gaps between the turns of the coil, as shown in Fig. 14 and cannot fairly be considered to be a tubular sleeve. Since certain claims recite a fastener in the form of a tubular sleeve, an evenly distributed force can be imparted over an elongate portion of the tube, ensuring that the tube is secured without restricting the lumen, as set out on Page 13 Lines 20-24 of the application.

Further, the applicant respectfully disagrees with the Examiner's assertion that the support disclosed in Potter is "configured when lengthened to grip a tube." Potter does not disclose or suggest lengthening the support to grip the tube. Any gripping of the tube by the support is simply provided by a frictional force between the tube and the plastic coating provided over the coiled wire (as stated in Column 7 Lines 14-17), and, as acknowledged by the Examiner in the Office Action of March 12, 2004, there is no disclosure of either lengthening the support to grip the tube or shortening the support to allow the tube to slide in Potter.

The argument that the support of Potter does not grip the tube is confirmed by the fact that the device of Potter is provided with spikes to hold the tube in position in relation

to the support, as disclosed in Column 7 Lines 21-23 and as Item 17 of Fig. 14. Alternatively, as disclosed in relation to Fig. 3, the tube may be held in position using a channel having barbs, such as those illustrated in Figs. 10 and 11. Hence the tube is not held in place by a gripping force from the support; instead it is held by spikes or barbs acting directly on the tube. Applicant notes that, disadvantageously, the spikes and barbs disclosed in Potter are likely to damage the tube and this disadvantage may be avoided by embodiments of the inventive system of the present application.

The coiled wire disclosed in Figs. 1 and 14 of Potter is not provided to prevent movement of the tube but is provided to support the endotracheal tube, to provide rigidity and to prevent kinking of the tube, as disclosed in Column 5 Lines 27-32, Column 2 Lines 49-50 and Column 7 Lines 16-17. The Examiner further asserts that “when the tube is shortened, the tube can freely slide along the length of the sheath.” However, Applicant respectfully submits that any shortening of the support will not allow the tube to freely slide along the length of the support since, as set out above, the devices disclosed in Potter are further provided with spikes or barbs to prevent any movement of the tube along the support.

Amended Claim 36 includes the further feature that the tubular sleeve comprises attachment means for attaching the sleeve to a patient, wherein the tubular sleeve is arranged to lengthen and grip the tube when the tube is pulled away from the attachment means. This feature is not disclosed or suggested in Potter. In contrast, pulling of the tube in the system disclosed in Potter would not cause any lengthening of the support, since the spikes and barbs would prevent movement of the tube.

Hence Potter does not disclose a fastener comprising a tubular sleeve, the tubular sleeve being of variable length and configured when lengthened to grip the tube and when shortened to slide along the tube. Nor does Potter disclose a sleeve having a perforated or foraminous wall defining a plurality of openings.

Withdrawal of the outstanding anticipation rejection based on Potter et al is accordingly respectfully requested.

**Rejection of the claims under 35 U.S.C 102(b) as being anticipated by Kite et al (US Pat# 4,754,685)**

The claims of the application are novel and non-obvious over Kite et al as set out below.

Claims 13 and 36 are not anticipated by Kite since Kite does not disclose or suggest the combination of a fastener for securing a tube to a patient and the tube itself.

Claim 49 is also not anticipated by Kite since Kite does not disclose or suggest providing attachment means for attaching the sleeve to a patient. In fact, the sleeve of Kite is not provided with any attachment means, but simply covers the wires or cables over which it is applied. Hence, even if the sleeve disclosed in Kite were to be used for securing a tube to a patient (although it is not conceded that this is either a possible or an obvious use of the sleeve disclosed), no means is provided whereby the sleeve can be attached to the patient. Hence, the sleeve would not provide resistance against removing the tube from the patient.

Hence, Kite does not disclose a fastener in combination with a tube for securing said tube to a patient, wherein the tube has a lumen and can transport fluid to or from a patient. Nor does Kite disclose attachment means for attaching the sleeve to a patient.

Withdrawal of the outstanding anticipation rejection based on Kite et al is accordingly respectfully requested.

**Rejection of Claim 39 under 35 U.S.C. 103(a) as being unpatentable over Kite et al or Potter et al**

As set out in our response dated June 14, 2004 to the Office Action of March 12, 2004, the rejection of Claim 39 as being unpatentable over Kite or Potter is respectfully traversed. Claim 39 is dependent on Claim 13, which has been amended as discussed above. Neither Kite nor Potter describes or suggests the claimed subject matter. Withdrawal of the outstanding obviousness rejection of Claim 39 is respectfully requested.

**Allowable subject matter**

It is noted, with appreciation, that Claims 17 and 32-33 are directed to allowable subject matter. With the amendments and comments presented herein, it is believed that all of the claims in the present application are now in allowable condition. Allowance of all claims is accordingly respectfully requested.

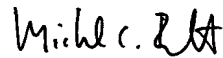
**Conclusion**

Applicant believes that this submission fully responds to all outstanding matters for this application. Applicant respectfully submits that the present application is in condition for allowance. Please contact the undersigned attorney at 512-536-3018 with any questions.

### **Petition for Extension of Time**

Applicant petitions for an extension of time of five months up to and including April 19, 2005, in which to respond to the present Office Action. A check is enclosed for the five-month extension of time. If the check is inadvertently omitted, or should any additional fees be required for any reason, or should an overpayment be included, the Office is authorized to deduct or credit Fulbright & Jaworski Deposit Account No. 50-1212/FIFW:019US/MCB.

Respectfully submitted,



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